



Food and Drug Administration
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September 8, 2014

K2M, Incorporated
Ms. Nancy Giezen
Manager, Regulatory Affairs
751 Miller Drive Southeast, Suite F1
Leesburg, Virginia 20175

Re: K141873

Trade/Device Name: Range/Mesa/Denali Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP
Dated: July 10, 2014
Received: July 11, 2014

Dear Ms. Giezen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K141873

Device Name

Range/Mesa/Denali Spinal System

Indications for Use (Describe)

RANGE /DENALI/MESA and SMALL STATURE and ARI are cleared for the following indications:

Non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system the Range Spinal System may also be used for the same indications as an adjunct to fusion.

Except for the ARI staples, the Range Spinal System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior noncervical fixation in pediatric patients. The Range Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) Summary
for the
RangeMesa/Denali Spinal System: Mesa Hooks**

This 510(k) summary for the Range/Mesa/Denali Spinal System is provided as required per 21 CFR 807.92

1. Submitter :

K2M, Inc.
751 Miller Drive SE,
Leesburg, VA 20175

Contact Person :

Nancy Giezen
K2M, Inc.
Telephone: 703-777-3155

Date Prepared: 07/09/2014

2. Tradename:

Range/Mesa/Denali Spinal System

Common Name:

Spinal Fixation System

Regulatory Class:

Class II, Class III (NKB)

Pedicle Screw Spinal System	(21 CFR 888.3070)	(NKB, OSH, MNH, MNI)
Spinal Intervertebral body fixation Orthosis	(21 CFR 888.3060)	(KWQ)
Spinal Interlaminar fixation Orthosis	(21 CFR 888.3050)	(KWP)

3. Predicate or legally marketed devices which are substantially equivalent :

- K2M Range/Mesa/Denali Spinal System (K070229, K121630, K133944)
- LDR Easyspine System (K061017)

4. Description of the device:

The Range Spinal System is a top-loading, multiple component, posterior (thoracic-lumbar) spinal fixation system which consists of pedicle screws, rods, hooks and rod connectors.

Materials: The devices are manufactured from Titanium and Cobalt Chrome per ASTM standards.

Function: The system functions as an adjunct to fusion to provide immobilization and stabilization of the posterior thoracic and lumbar spine.

Purpose of Submission: To add sterile packaging.

5. Intended Use:

RANGE /DENALI/MESA and SMALL STATURE and ARI are cleared for the following indications:

Non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor: pseudarthrosis: and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system the Range Spinal System may also be used for the same indications as an adjunct to fusion.

Except for the ARI staples, the Range Spinal System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis when used for posterior noncervical fixation in pediatric patients. The Range Spinal System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

6. Comparison to predicate and legally marketed devices :

The design features and sizing of the components were previously compared to predicate devices. Performance evaluations were previously conducted on constructs representing the worst case components (including static torsion, static compression and dynamic compression bending in accordance with ASTM F1717) and the Range Spinal System was found to be substantially the same as predicate devices. The methods used for sterilization are also equivalent to predicate devices.

8. Conclusion:

There are no significant differences between the Range/Mesa/Denali System and other devices currently being marketed which would adversely affect the use of the product.